UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,097	01/18/2000	JURG ZIMMERMANN	4-30096/A	5856

1095 7590 03/12/2002

THOMAS HOXIE
NOVARTIS CORPORATION
PATENT AND TRADEMARK DEPT
564 MORRIS AVENUE
SUMMIT, NJ 079011027

EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 17

Application Number: 09/463097
Filing Date: January 18,2000
Appellant(s): Zimmermann et al.

Mr.George R. Dohmann
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 1/7/02.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does contains a statement that there are no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is substantially correct. A correct statement of the status of the claims is as follows: Claim 12, which was formerly rejected under 35 USC 112, par.two and under 35 USC 103 for reasons given in previous actions, is no longer rejected. With regard to the par.two rejection, upon review of the specification the digestion vs dissolution processes employing other methanesulfonate (Ms) forms of instant compound embraced in 12 are done at different temperatures and thus the reaction parameters are not completely identical as originally perceived. With regard to the 103 rejection over Zimmermann in view of Yu, appellants' comment that the preparation of the instant beta form is not made obvious by the inclusion of Yu, is persuasive in light of In re Ochiai (37 USPQ 2d 1127) . Thus claim 12 is allowed and the claims still on appeal are 1-8,10,13-16.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. However 2 issues have been removed as discussed above in section (3).

(7) Grouping of Claims

Appellant's brief includes a statement that the following sets of claims stand or fall together with respect to the art rejection (over Zimmermann) and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8):

1. Claims 1-3,10 and 13;

2. Claims 4-5;

3. Claims 6-8;

4. Claims 15-16;

5. Claim 14 (stands or falls alone).

However with respect to the 112 rejection under par.two it not stated that claims rejected (1,4-8,15-16) should be treated separately and thus they stand or fall together. Claim 14 is the only claim rejected under par.one.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,521,184	ZIMMERMANN	May 28,1996

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 1, 4-8,15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4,5,7 and 8 are not seen to materially differ from each other since for these claims the same compound is being claimed with the same purity requirement

but only further characterized in terms of X-ray diffraction data and/or other structure determination techniques. Claim 6 is not seen to further limit claim 1 based solely on X-ray diffraction peak recited therein. The same also applies for 15 vs 16 since 16 (dependent on 15) only recites additional X-ray peaks and is the same data as for claim 7.

In traversing the 112 rejection, appellants rely on the inclusion of these characterization data but do not show how this data changes the scope of these compound claims. Specification does not make any distinctions. Thus the urged differences in scope is still unclear.

B. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 14 (presented by Amendment B) which is directed to a method of treating any and all types of tumors is not enabled based solely on the assay testing reported in the specification beginning on p.10 from which it is urged a variety of tumors (sarcomas, colon,breast, prostrate,lung) can be treated. Displaying PDGF or other

tyrosine kinase inhibitory activity is not synonymous with successful treatment of all tumor-related diseases in man. Note In re Buting 163 USPQ 689 in which it was decided that a showing for two types of cancer (employing in vivo testing) was not a sufficient showing for the list of tumors claimed. Broad-based anti-tumor agents are not well known in general and applicants have not provided evidence that their compound is the exception to the norm.

Appellants mention for the first time in their brief that the neutral racemic form of their crystalline Ms salt (named alternately as Gleevec or Imatinib) has been described for the treatment of "certain types of cancers" but none are or were ever identified to the examiner during prosecution of the case. Thus in the absence of any meaningful data such as tumor regression testing in murine hosts as was done in the Buting case, the claim is not enabled.

C. Claims 1-8,10,13-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zimmermann (US'184). The commonly assigned patent describes the free form of instant compound along with a list of intended salts including the methanesulfonate salt for various uses including as an antitumor agent. See eg.21 and claim 23. The list of 32 recited salts

in col.3 coupled with claim 23 (or eg.21) constitutes an anticipation of the methanesulfonate salt in view of the narrow genus present. See In re Petering 133 USPQ 275;In re Schaumann 197 USPQ 5;In re Sivaramakrishan 213 USPQ 441 regarding anticipation requirements. It is recognized that appellcants are claiming a specific crystalline form and while Zimmermann is silent as to the existence of one or more forms for its salts, applicants must show that employing routine procedures for making the Ms salt as relied on by Zimmermann (see col.19), the instant beta form is not inherently produced. See In re Fitzgerald 205 USPQ 594; In re Grose 201 USPQ 57: and In re Best 195 USPQ 430.

If the genus is deemed too large to place the instant mesylate salt in the public's possession, it is otherwise an obvious variant in view of the express teaching to employ said salt among others for the uses taught for the free form. See last paragraph in col.3 and first one in col.4. Thus it would have been obvious to one skilled in the art at the time the invention was made to employ instant mesylate salt for use as an anti-tumor agent in view of the equivalency teaching outlined above.

In traversing the 102/103 rejections appellants first urge there is no description of the Ms salt *per se* since the teachings of Zimmermann are too broad and do not particularly point to the specific salt forms and thus the case law on narrow genuses is not applicable herein. The examiner disagrees. While broader disclosures may exist in the patent, the examiner is not obligated to rely on such when narrower ones are also present. Also it is not agreed that the salt forms are not particularly contemplated when in col. 3,lines 61-67 the following is stated: "Owing to the close relationship between the novel compounds in free form and in the form of their salts....hereinbefore and hereinafter any reference to the free compounds should be understood as including the corresponding salts,where appropriate and expedient." . Any more explicit a direction would be the ultimate preparation of the salts. In fact the court in Petering went on to say that even the corresponding isomers of the 20 preferred compounds would be considered anticipatory since the existence of these isomers would be well known to those of ordinary skill. See left column of p.280,last paragraph.Thus the naming of the free base coupled with the particular salts recited in col.3 constitutes an anticipation for each and every of recited salts which include the methanesulfonate salt. The second point raised by

appellants is that even if the Ms salt could be held to be anticipated or obvious, Zimmermann does not teach the particular crystalline form being claimed. The burden is on appellants not the examiner to show that their particular salt form (the beta form) cannot be made following routine conditions. The case law cited by the examiner supports this contention of who has the burden of proof. While the Ms salt was not made in Zimmermann, there exists a presumption that the Ms salt in Zimmermann can be made employing the routine procedure outlined in col.19 since the salt has been claimed and applicants are enjoying a monopoly on this unmade compound. At any rate the test for anticipation is not if a compound is actually made but if its preparation is within the knowledge of those of ordinary skill. See Ex parte A 17 USPQ 2d 1716. Zimmerman relies on routine preparation (adding methanesulfonic acid to the base in any solvent) as pointed out previously in col.19. Appellants' list of alternate processes for making one crystalline form over another also relies on a whole range of solvents. It is irrelevant and as a matter of law not necessary that Zimmerman even if he made the mesylate salt of claim 11, chose not to characterize it by subjecting it to an X-ray diffraction study or any other testing such as hygroscopicity. The examiner has correctly put the burden on appellants to

show that their compound cannot be made employing routine reaction conditions that would (with some trial and error) ultimately produce the crystalline form claimed herein for which applicants' assignee continues to enjoy a monopoly. Also see In re Best 195 USPQ 430 at 433 which has the following quote " Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may, in fact, be an inherent characteristic in the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." On the same page and on p.434 the decision reemphasizes this point in the following quote: "Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." . If appellants' reasoning on p.8, second paragraph of the brief were the law, then it would appear wise (if not beneficial to public interest) for all potential patentees to withhold working examples from their patent disclosures .

Appellants rely on Glaxo v. Novopharm 34 USPQ 2d 1565 and urge Grose is consistent with it but it is not seen how since appellants unlike the Glaxo case, provide no evidence that following routine conditions- i.e. dissolving the free form in a variety of solvents in the presence of methanesulfonic acid (as Zimmermann teaches) one would not (in a given solvent) obtain the form claimed herein. In fact appellants own disclosure shows in one of its alternate processes (one not claimed) the preparation of the beta form employing the procedure of Zimmerman. See eg.2 on p.19.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

E Bernhardt

EMILY BERNHARDT
PRIMARY EXAMINER
GROUP ~~120~~ 1600

Emily Bernhardt
March 9, 2002

CONFEREES:

Alan L. Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mukund J. Shah

MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 160